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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/795,819 | 03/08/2004 | Vladimir Bakhutashvili | 627-B-US | 2803 |

7590 06/20/2005

Albert Wai-Kit Chan
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| EXAMINER | |
|---|---|
| DAVIS, RUTH A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/795,819 | BAKHUTASHVILI, VLADIMIR | |
| | Examiner | Art Unit | |
| | Ruth A. Davis | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *25 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,23,24,65,67 and 85-98* is/are pending in the application.

4a) Of the above claim(s) *23,24,67,97 and 98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,65 and 85-96* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/05;9,4,3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I, claims 2, 3, 65 and 85 – 98 in the reply filed on March 25, 2005 is acknowledged. The traversal is on the grounds that the methods of groups II and III use the composition of group I thus are not independent. Applicant additionally argues that the groups are searchable together, there is no burden and that the groups have the same search. This is not found persuasive because the claims are independent and distinct as stated in the previous office action. Specifically, the groups are independently claimed, the methods are distinct from the composition in that one would not have to practice the methods to use the composition alone. In addition, as evidenced by the separate classification, the searches are not the same and would cause undue burden on examiner. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23, 24, 67, 97 and 98 are withdrawn from consideration, as being drawn to non-elected subject matter. Claims 2, 3, 65 and 85 – 96 have been considered on the merits.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2, 3, 65 and 85 – 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant claims a composition, however does not clearly set forth what constitutes the composition. By claiming the composition solely in terms of function and where the composition may be obtained, it is impossible to determine the scope of the claims since the composition is not required to contain any specific component.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2, 3, 65 and 85 – 96 are rejected under 35 U.S.C. 102(a) as being anticipated by Drugs of the Future (1999, 24(9)).

Applicant claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and is made by purifying the product. The product is further

lyophilized. The composition further comprises a pharmaceutically effective agent selected from a disclosed group; a physiologically acceptable carrier suitable for topical, parenteral or gastrointestinal administration. Applicant additionally claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and has peaks set forth in figure 3, 2, at least one of peak in figure 3 or 2. Finally applicant claims a composition obtainable from human or animal amniotic tissues and is made by purifying the product, wherein the composition is capable of inhibiting or killing cancers cells, is antagonistic to H1 histamine receptors, is inhibitory to A2 phospholipase activity, is protective to cardiomyocytes, and protects against effects of tumor necrosis factor.

Drugs of the Future teaches a composition comprising plaferon (abstract, p.974) wherein the composition has anti-proliferative activity (of inhibits/kills cancer cells), is protective to myocardial infarction (or protects cardiomyocytes), and is administered to patients (or has a physiologically acceptable carrier for parenteral administration) (p.974-975).

Since plaferon is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is

the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

6. Claims 2, 3, 65 and 85 – 96 are rejected under 35 U.S.C. 102(a) as being anticipated by Bakhutashvili et al. (International J immunorehab 1999).

Applicant claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and is made by purifying the product. The product is further lyophilized. The composition further comprises a pharmaceutically effective agent selected from a disclosed group; a physiologically acceptable carrier suitable for topical, parenteral or gastrointestinal administration. Applicant additionally claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and has peaks set forth in figure 3, 2, at least one of peak in figure 3 or 2. Finally applicant claims a composition obtainable from human or animal amniotic tissues and is made by purifying the product, wherein the composition is capable of inhibiting or killing cancers cells, is antagonistic to H1 histamine receptors, is inhibitory to A2 phospholipase activity, is protective to cardiomyocytes, and protects against effects of tumor necrosis factor.

Bakhutashvili teaches a composition of plaferon LB, obtained from human amniotic tissues (abstract). The composition comprises other interferons (or pharmaceutically effective

agents) (abstract) and exhibits activities as claimed by applicant (abstract). Bakhutashvili teaches the plaferon LB is administered with other drugs (abstract) and is administered to patients (or has a physiologically acceptable carrier for parenteral administration) (p.51)

Since plaferon LB is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

7. Claims 2, 3, 65 and 85 – 96 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnson et al. (International Academy of Cardiology Inc, 1999).

Applicant claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and is made by purifying the product. The product is further lyophilized. The composition further comprises a pharmaceutically effective agent selected from a disclosed group; a physiologically acceptable carrier suitable for topical, parenteral or gastrointestinal administration. Applicant additionally claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and has peaks set forth in figure 3, 2, at least one of peak in figure 3 or 2. Finally applicant claims a composition obtainable from human or animal amniotic tissues and is made by purifying the product, wherein the composition is capable of inhibiting or killing cancers cells, is antagonistic to H1 histamine receptors, is inhibitory to A2 phospholipase activity, is protective to cardiomyocytes, and protects against effects of tumor necrosis factor.

Johnson teaches a composition of plaferon LB wherein it is administered intravenously (abstract) (or is a composition comprising a pharmaceutically effective agent and a physiologically acceptable carrier suitable parenteral administration).

Since plaferon LB is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

8. Claims 2, 3, 65, 85 – 86 and 89 – 96 are rejected under 35 U.S.C. 102(a) as being anticipated by Pantsulaya et al. (Proc Georgian Acad Sci Biol Ser, 199).

Applicant claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and is made by purifying the product. The product is further lyophilized. The composition further comprises a pharmaceutically effective agent selected from a disclosed group. Applicant additionally claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and has peaks set forth in figure 3, 2, at least one of peak in figure 3 or 2. Finally applicant claims a composition obtainable from human or animal amniotic tissues and is made by purifying the product, wherein the composition is capable of inhibiting or killing cancers cells, is antagonistic to H1 histamine receptors, is inhibitory to A2 phospholipase activity, is protective to cardiomyocytes, and protects against effects of tumor necrosis factor.

Pantsulaya teaches compositions comprising plaferon LB obtained from amniotic membranes, wherein the composition exhibits the claimed activities (abstract, p.75). The compositions of plaferon LB have peaks set forth in figures 3, 2, or at least one of peak in figures 3 or 2 (p.77).

Since plaferon LB is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

9. Claims 2, 3, 65 and 85 – 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakhutashvili et al. (Georgian Symposium, 1995).

Applicant claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and is made by purifying the product. The product is further lyophilized. The composition further comprises a pharmaceutically effective agent selected from a disclosed group; a physiologically acceptable carrier suitable for topical, parenteral or gastrointestinal administration. Applicant additionally claims a composition that has apoptosis modulating activity, is obtainable from human or animal amniotic tissues and has peaks set forth in figure 3, 2, at least one of peak in figure 3 or 2. Finally applicant claims a composition obtainable from human or animal amniotic tissues and is made by purifying the product, wherein the composition is capable of inhibiting or killing cancers cells, is antagonistic to H1 histamine receptors, is inhibitory to A2 phospholipase activity, is protective to cardiomyocytes, and protects against effects of tumor necrosis factor.

Bakhutashvili teaches a composition of plaferon LB, wherein the composition is obtained from a placenta, and has physiologically active substances (or is a pharmaceutically effective agent) (abstract, p.189). Bakhutashvili teaches the composition is administered to patients (or has a physiologically acceptable carrier for parenteral administration).

Since plaferon LB is obtainable from amniotic tissues and exhibits each of the claimed activities and each of the peaks as in figures 2 and 3, the compositions are the same. In addition, while the reference does not specifically identify each of the claimed activities, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. (MPEP 2112)

In addition, although the reference does not teach how the product is obtained, the patentability of a product does not depend on its method of production. If the claimed product is the same or obvious from a product in the prior art (i.e. the product disclosed in the cited reference), the claim is unpatentable even though the reference product was made by a different process. When the prior art discloses a product which reasonably appears to be identical with or slightly different than the claimed product-by-process, rejections under 35 U.S.C 102 and/or 35 U.S.C 103 are proper. (MPEP 2113)

Thus, the reference anticipates the claimed subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis
June 11, 2005
AU 1651